

## REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1 and 9-12 are pending. The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. Support for preventing hearing impairment may be found, inter alia, at page 4, lines 6-8, of the specification.

### *35 U.S.C. 112 – Enablement*

The Patent Office has the initial burden to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04, and the cases cited therein. It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, 169 USPQ 367, 370 (C.C.P.A. 1971). Specific technical reasons are always required. See M.P.E.P. § 2164.04.

Claims 1-7 and 9 were rejected under Section 112, first paragraph, because it was alleged that the specification does not reasonably provide enablement for “any composition or method as broadly claimed.” Applicants traverse.

Although not acquiescing to the Examiner’s objection, he did find that the specification was enabling for “a composition comprising a plasmid encoding HGF encapsulated in hemagglutinating virus of Japan envelope protein and treating hearing impairment by administering the composition intrathecally to a patient with hearing impairment” and Applicants amend claims 1 and 9 to advance prosecution in this application.

Withdrawal of the enablement rejection made under Section 112, first paragraph, is requested because it would not require undue experimentation for a person of skill in the art to make and use the claimed invention.

### *35 U.S.C. 112 – Definiteness*

Claims 2-7 and 9 were rejected under Section 112, second paragraph, as being allegedly indefinite. Applicants traverse because cancellation of claims 2-7 and amendment of claim 9 moots the Examiner’s objection.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

*35 U.S.C. 102 – Novelty*

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1-7 were rejected under Section 102(e) as allegedly anticipated by Wu et al. (US 2001/0039048). Applicants traverse.

Claim 1 requires a pharmaceutical composition comprising a plasmid encoding hepatocyte growth factor (HGF) encapsulated in hemagglutinating virus of Japan envelope protein. Wu discloses a plasmid encoding HGF and an adenoviral particle. But the cited document does not teach all the limitations of Applicants' claim 1. Therefore, Wu does not anticipate the pending claim.

Claims 1-2 and 5-7 were rejected under Section 102(a) as allegedly anticipated by Guo et al. (CN 1358543). Applicants traverse.

Claim 1 requires a pharmaceutical composition comprising a plasmid encoding hepatocyte growth factor (HGF) encapsulated in hemagglutinating virus of Japan envelope protein. Guo discloses a plasmid encoding HGF but no viral particle. Therefore, the cited document does not teach all the limitations of Applicants' claim 1 and Guo does not anticipate the pending claim.

Withdrawal of the Section 102 rejections is requested because the cited documents fails to disclose all limitations of the claimed invention.

*Conclusion*

Having fully responded to all of the pending objections and rejections contained in this Office Action, Applicants submit that the claims are in condition for allowance and

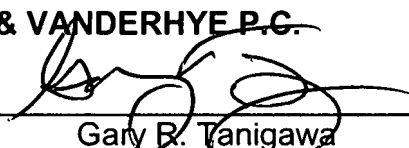
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earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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